

REMARKS

Claims 1-8 and 24-32 have been cancelled. New claims 33-49 have been added and are now active in this case.

All of the above amendments are fully supported by the claims and disclosure as originally filed. Hence, no new matter has been added.

Further, the newly added claims correspond to the previous election of species.

REQUEST FOR RECONSIDERATION

The outset, applicants gratefully acknowledge the withdrawal of the previous grounds of rejection under 35 U.S.C. §102(b) in view of Lin et al. as well as the previous ground of rejection under 35 U.S.C. 103(a) in view of Lin et al., Clark et al. and Smith et al.

Ichthyophthiirus multifiliis is a ciliated ectoparasitic protozoan that causes white spot disease, for example, which causes high mortality rates among many freshwater fish. In the past, fish manifesting clinical signs of infection have been treated with chemicals, which unfortunately remain in the fish tissue in residual amounts which are dangerous to consumers of the fish.

The present invention avoids this problem by providing a vaccine for immunizing fish against ciliated ectoparasitic protozoans containing an effective amount of a fusion protein expressed from a recombinant DNA sequence for immobilization antigen, repeat I of *Ichthyophthiirus multifiliis*, wherein the fusion protein is at least one selected from the group consisting of SEQ. ID Nos. 1-17.

Importantly, the present invention provides a vaccine which contains a fusion protein expressed from a recombinant DNA sequence for immobilization antigen, repeat I of

Ichthyophthiirius multifiliis as described above.

Claims 1-8 and 24 stand rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al. 1992 (PNAS USA, July, 1992, 89:6363-6367) and He et al. 1997 (Aquaculture, 1997, 158:1-10).

However, none of these references, either above or in combination, would place one skilled in the art in possession of the present invention.

Specifically, Clark has been cited as expressing the immobilization antigen, i.e., iAgI. This reference is also cited as teaching that

...because the i-antigens of the Ich interact with the immune system of fish, they have potential as protective immunogens and may be of practical use in the treatment of a pathogen with major impact on aquaculture worldwide. See page 6367, column 2.

However, this reference clearly fails to disclose or suggest the formation of a vaccine for immunizing fish against ciliated ectoparasitic protozoans. In contrast, the present specification directed to the preparation of a vaccine and its application in fish.

Furthermore, the present specification clearly demonstrates the effectiveness of the vaccine of the present invention.

However, even more fundamentally, the fusion protein of the present vaccine is expressed from a recombinant DNA sequence from the immobilization antigen, repeat I of *Ichthyophthiirius multifiliis*. Thus, the overall sequence of the overall recombinant DNA sequence (SEQ. ID No. 1, for example) is different from the sequence of Figure 1 of Clark et al.

Hence, the fusion protein used in the present vaccine could not be the same as that of Clark et al. even if the two proteins are both considered to exhibit the same function, i.e., to agglutinate the ciliated protozoan.

Further, Clark et al. fails to provide any description – and thus, enablement – of how any vaccine could be prepared. From In re O'Farrell, 7 U.S.P.Q. 2d 1673 (Fed. Cir. 1988), it is clear

that, particularly for biotechnological inventions, a reference must contain an enabling methodology for practicing a claimed invention before the reference can render the claimed invention obvious. This conclusion is a proper conclusion and reflects the well-known distinction between “obvious” and merely “obvious to try,” the latter of which has long been discredited as a test for obviousness. Thus, under In re O’Farrell, the present invention would clearly not have been obvious to one skilled in the art at the time it was made in view of Clark et al.

Moreover, in view of the declaration of record, it is quite clear that He et al. is not available as a reference against the present invention.

In more detail, the Declaration of record over and establishes and the present inventors are the “true and complete” authors of the cited He et al. article and the remaining two listed authors are not inventors of the claimed subject matter.

Hence, the He et al. article is not a valid reference against the present invention.

Hence, this ground of rejection is unsustainable and should be withdrawn.

Claims 1-8 and 24 stand rejected under U.S.C. 102(b) as being anticipated by He et al.

However, in view of the declaration of record, and the above remarks, it is clear that this publication is not available as a reference against the present invention.

Hence, this ground of rejection is believed to be unsustainable and should be withdrawn.

Claims 1-8 and 24 stand rejected under 35 U.S.C. 112, second paragraph.

In view of the above amendments, this ground of rejection is believed to be unsustainable and should be withdrawn.


Accordingly, in view of all of the above, it is believed that the present application now stands in condition for allowance. Early notice to this effect is earnestly solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby

made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 07-1337 and please credit any excess fees to such deposit account.

Respectfully submitted,

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